

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE  
(REV. 2-2005)

**TRANSMITTAL LETTER TO THE UNITED STATES**  
**DESIGNATED/ELECTED OFFICE (DO/EO/US)**  
**CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER

RLL-317US

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

**10/539130**INTERNATIONAL APPLICATION NO.  
**PCT/IB2003/005945**INTERNATIONAL FILING DATE  
**15 December 2003**PRIORITY DATE CLAIMED  
**16 December 2002**

TITLE OF INVENTION

**PURE LEVOFLOXACIN HEMIHYDRATE AND PROCESSES FOR PREPARATION THEREOF**

APPLICANT(S) FOR DO/EO/US

**SHARMA et al.**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

**Items 13 to 23 below concern document(s) or information included:**

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. **EV 674777028 US**
23. ☒ Other items or information:  
**Certificate of Express Mail**  
**Return Postcard**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/539130</b>		INTERNATIONAL APPLICATION NO. <b>JP2003/005945</b>		ATTORNEY'S REGISTRATION NUMBER <b>RLL-317US</b>	
The following fees are submitted:				<b>CALCULATIONS</b>	<b>PTO USE</b>
24. <input checked="" type="checkbox"/> Basic national fee .....		\$300	\$	\$300.00	
25. <input checked="" type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4). ....		\$100	\$	\$200.00	
All other situations. ....		\$200			
26. <input checked="" type="checkbox"/> Search fee .....					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority .....		\$100			
International Search Report prepared and provided to the Office .....		\$400	\$	\$400.00	
All other situations. ....		\$500			
<b>TOTAL OF 24, 25 and 26 =</b>			\$	<b>\$900.00</b>	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE		
- 100 =	0	/50 =	0	x \$250.00	\$
					\$0.00
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	25 - 20 =	5	x \$50.00	\$	\$250.00
Independent claims	5 - 3 =	2	x \$200.00	\$	\$400.00
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00				\$	\$0.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	<b>\$1,550.00</b>
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	\$0.00
<b>SUBTOTAL =</b>				\$	<b>\$1,550.00</b>
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	\$0.00
<b>TOTAL NATIONAL FEE =</b>				\$	<b>\$1,550.00</b>
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +				\$	\$0.00
<b>TOTAL FEES ENCLOSED =</b>				\$	<b>\$1,550.00</b>
				<b>Amount to be</b>	\$
				<b>Amount to be</b>	\$
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>50-0912</u> in the amount of <u>\$1,550.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-0912</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.</p>					
<p><b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO:</p> <p>Jayadeep R. Deshmukh, Esq. Reg. No. 34,507 Customer No. 26815</p>					
				<i>William D. Hare</i>	
				SIGNATURE	
				William D. Hare	
				NAME	
				44,739	
				REGISTRATION NUMBER	

10/539130

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): SHARMA *et al.* JC20 Rec'd PCT/PTO 1 5 JUN 2005  
International Application No.: PCT/IB2003/005945  
International Filing Date: 15 December 2003  
Title: PURE LEVOFLOXACIN HEMIHYDRATE AND  
PROCESSES FOR PREPARATION THEREOF

**CERTIFICATE OF EXPRESS MAILING**

I hereby certify that the following correspondence:

- Transmittal Letter to the US DO/EO Concerning a Filing Under 35 USC 371
- Unexecuted Combined Declaration and Power of Attorney
- Preliminary Amendment
- Copy of the International Search Report
- Copy of the International Preliminary Examination Report
- Postcard

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 15, 2005.

Michelle Morgan

(Name of Person Mailing Correspondence)

*Michelle Morgan*

(Signature)

EV 674777028 US

(Express Mail Mailing Label Number)

EV674777028US